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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/748,435	12/27/2000	Konomu Hirao	10873.632US01	4173

23552 7590 09/12/2002

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EXAMINER

ALEXANDER, LYLE

ART UNIT	PAPER NUMBER
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1743

DATE MAILED: 09/12/2002

6

Please find below and/or attached an Office communication concerning this application or proceeding.

T.P

Office Action Summary

Application No.

09/748,435

Applicant(s)

HIRAO ET AL.

Examiner

Lyle A Alexander

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on _____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
 If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
 * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
 a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) *jj*
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4-5.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4,6-7,10-17,19-20 and 24 rejected under 35 U.S.C. 102(b) as being clearly anticipated by Bunce et al.

Bunce et al. teach a device for testing whole blood for analytes of interest. The device includes an asymmetric porous membrane, to remove the red blood cells from the sample, and an analytical region. In fig. 5 an embodiment it taught where the asymmetric porous membrane(51) is folded to create a "U" shape having two grooves on the bottom that contacts assay strip(512). The side regions(514a) and (514b) support membrane(51). Funnel(52) receives the blood and supplies it to the membrane(51). Funnel(52) is supported by spring forms(55a) and (55b) which holds the funnel in the inner wall of the membrane(51).

Claims 1,3, 6-11, 14-21 and 24 rejected under 35 U.S.C. 102(b) as being clearly anticipated by Douglas et al.

Douglas et al. teach a test device comprising a filtration membrane to remove red blood cells and means for analysis. The membrane is taught as having a hydrophilic surface that enhances the blood separation capabilities of the membrane. The membrane is preferably a polyethersulfone which has been read on the claimed

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polysulfone. Columns 21-22 teach various dimension of the device that have been read on the claimed dimensions.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

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Claims 5,18 and 21-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bunce et al.(USP 5,916,521).

Bunce et al. are silent to the claimed pore sizes, the relative size of the device and the holder being transparent or having a slit.

The court decided In re Boesch (205 USPQ 215) that optimization of a result effective variables is ordinarily within the skill of the art. A result effective variable is one that has predictable and well known results.

It is notoriously well known in the art that red blood cell separation is achieved by asymmetric membranes having the maximum pore sizes between 10 microns and 1mm and the minimum 0.2-5 microns (see the cited prior art EP 0336483 in the last paragraph of page 6). The selection of the pore sizes to accomplish the taught function of separating red blood cells from whole blood is a result effective variable. It would have been within the skill of the art to modify Bunce et al. to select any well known range of pore sizes capable of separating red blood cells such as a maximum pore size of 30-300 microns and a minimum of 1-5 microns to achieve the well known and expected function of blood cell separation as optimization of a result effective variable.

Similarly, the choice the size of the device, making a material transparent or to include a slit are also result effective variables. It is desirable to make plastics transparent so the progress of a colored sample, such as the taught blood, through the device may be observed. It is desirable to make a slit structure because it is easy to manufacture.

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It would have been within the skill of the art to modify Bunce et al. to make the device have a spaced height of 0.05-3000 microns, incorporate a transparent material and use of a slit structure to gain the above advantages as optimization of a result effective variable.

Claims 8-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bunce et al. in view of Douglas et al.

See Bunce et al. *supra*.

See Douglas et al. *supra*.

Bunce et al. are silent to the claimed polysulfone membrane and a membrane with a hydrophilic surface.

Douglas et al. teach in column 9 lines 4-6 that hydrophilic membranes have enhanced blood separation capabilities and in line 30 of the same column a preferred membrane with these characteristics is a polyethersulfone polymer.

It would have been within the skill of the art to modify Bunce et al. in view of Douglas et al. to use a polysulfone membrane, such as the polyethersulfone polymer membrane taught by Douglas et al. to gain the taught advantages of enhanced blood separation capabilities.

Claims 2 and 12-13 rejected under 35 U.S.C. 103(a) as being unpatentable over Douglas et al. in view of Bunce et al.

See Douglas and Bunce et al. *supra*.

Douglas et al. is silent to forming the separation membrane to have a groove.

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Bunce et al. teach in column 8 lines 33+ that bending the membrane into a "U" shape with two grooves at the bottom has the advantage of increasing the filtration capacity of the membrane.

It would have been obvious to modify Douglas et al. in view of Bunce et al. and make the filter membrane in the shape of a "U" which results in grooves at the bottom to gain the above advantages.

Claims 4-5 and 22-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Douglas et al.

Douglas et al. are silent to the claimed pore sizes, the relative size of the device and the holder being transparent or having a slit.

The court decided In re Boesch (205 USPQ 215) that optimization of a result effective variables is ordinarily within the skill of the art. A result effective variable is one that has predictable and well known results.

It is notoriously well known in the art that red blood cell separation is achieved by asymmetric membranes having the maximum pore sizes between 10 microns and 1mm and the minimum 0.2-5 microns (see the cited prior art EP 0336483 in the last paragraph of page 6). The selection of the pore sizes to accomplish the taught function of separating red blood cells from whole blood is a result effective variable. It would have been within the skill of the art to modify Douglas et al. to select any well known range of pore sizes capable of separating red blood cells such as a maximum pore size of 30-300 microns and a minimum of 1-5 microns to achieve the well known and expected function of blood cell separation as optimization of a result effective variable.

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Similarly, the choice of using a transparent material or to include a slit are also result effective variables. It is desirable to make plastics transparent so the progress of a colored sample, such as the taught blood, through the device may be observed. It is desirable to make a slit structure because it is easy to manufacture.

It would have been within the skill of the art to modify Douglas et al. incorporate a transparent material and use of a slit structure to gain the above advantages as optimization of a result effective variable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lyle A Alexander whose telephone number is 703-308-3893. The examiner can normally be reached on Monday, Wednesday and Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 703-308-4037. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9319 for regular communications and 703-872-9311 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0651.



Lyle A Alexander
Primary Examiner
Art Unit 1743

September 11, 2002